

We Claim:

1. A device for compacting cancellous bone comprising a wall made from an elastomer material and including a region preformed with a normally expanded shape outside bone.

2. A device according to claim 1 wherein the wall includes a second region, spaced from the first-defined region, and preformed with a normally expanded shape outside bone.

3. A device according to claim 2 wherein the first-defined region and the second regions, when further expanded beyond their respective normally expanded shapes to reach a given inflation volume, present a maximum diameter less than a sphere expanded to an equal inflation volume. A

4. A device according to claim 2 wherein the wall includes a third region, preformed with a normally expanded shape outside bone, and positioned between the first-defined region and the second region.

5. A device according to claim 4 wherein the first-defined region, the second region, and the third region, when expanded beyond their respective normally expanded shapes to reach a given inflation volume, present a maximum diameter less than a sphere expanded to an equal inflation volume.

6. A device according to claim 1 wherein the expandable region has non-uniform wall thickness.

7. A device according to claim 1 wherein the expandable region includes a further expanded shape, outside bone, having a diameter greater than the normally expanded shape.

8. A device according to claim 7 wherein the expandable region has a further

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9. A device according to claim 1 wherein the elastomer material has an ultimate elongation of greater than about 300%.

11. A device according to claim 1
wherein the elastomer material is resistant to
abrasion by cancellous bone.

13. A device according to claim 1
wherein the elastomer material possesses a
rotating drum abrasion resistance value of less than about
70 mm³ for resistance to abrasion by cancellous bone.

15. A device according to claim 1
wherein the elastomer material possesses a Shore
hardness value of less than about 100 A for elastomeric
expansion within and resistance to abrasion by cancellous
bone.

17. A device for compacting cancellous bone comprising a body having a first diameter, and an expandable region formed from the body with a shape having, outside bone, a normally expanded diameter greater than the first

5 diameter, and a further expanded shape having a diameter, outside bone, greater than the normally expanded diameter, the further expanded shape inside bone substantially corresponding with the further expanded shape outside bone.

18. A device according to claim 17 wherein the body has a first wall thickness, and wherein the expandable region has a wall thickness less than the first wall thickness.

19. A device according to claim 17 wherein the normally expanded diameter is at least about 5% greater than the first diameter.

20. A device according to claim 17 wherein the expandable region includes an elastomer material.

21. A device according to claim 20 where the elastomer material includes polyurethane.

22. A device according to claim 17 wherein the expandable region includes material that is resistant to abrasion by cancellous bone.

23. A device for compacting cancellous bone comprising a wall including a region preformed to possess a normally expanded shape outside bone, which is further expandable to an enlarged shape outside bone at substantially constant pressure.

24. A device according to claim 23 wherein the region is expandable to an enlarged shape inside bone at substantially constant pressure having a magnitude determined by resistance of cancellous bone to compaction.

25. A device according to claim 23 wherein the region has an enlarged shape, when expanded inside bone, which substantially conforms to the enlarged shape outside bone.

26. A device according to claim 23

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wherein the region includes an elastomer material.

27. A device according to claim 26 wherein the elastomer material includes polyurethane.

28. A device according to claim 23 wherein the region includes material that is resistant to abrasion by cancellous bone.

29. A device for compacting cancellous bone comprising an expandable wall including material that is resistant to abrasion by cancellous bone.

30. A device for compacting cancellous bone comprising an expandable wall and a material covering the expandable wall that is resistant to abrasion by cancellous bone.

31. A device according to claim 29 or 30 wherein the material includes polyurethane material.

32. A device according to claim 29 or 30 wherein the material includes elastomer material.

33. A device according to claim 29 or 30 wherein the material possesses a rotating drum abrasion resistance value of less than about 70 mm³.

34. A device according to claim 29 or 30 wherein the material has an abrasion resistance value of less than about 90 mg loss.

35. A device according to claim 29 or 30 wherein the material has a tear strength value of greater than about 280 lbf/in.

36. A device according to claim 29 or 30 wherein the material has a durometer of shore hardness less than about 100 A.

37. A device for compacting cancellous bone comprising a tube made of an elastomer material, the tube including a first section having a first diameter and a second section preformed by heat and pressure to a second

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instructions for using the device according to a method comprising the step of expanding the device inside

bone to compact cancellous bone and form a cavity.

46. A system according to claim 45 wherein the method for use further includes the step of filling the cavity with material.

47. A system according to claim 46 wherein the method for use further includes the step of removing the device from bone prior to the filling step.

48. A system according to claim 46 wherein the material comprises bone cement.

49. A system according to claim 46 wherein the material comprises synthetic bone substitute.

50. A system according to claim 46 wherein the material comprises a flowable material that sets to a hardened condition.

51. A system according to claim 46 wherein the material comprises allograft tissue.

52. A system according to claim 46 wherein the material comprises autograft tissue.

53. A system according to claim 46 wherein the material comprises medication.

54. A device for insertion into a vertebral body having a top plate and a bottom plate, the device including an expandable wall that, when expanded inside the vertebral body, moves at least one of the top and bottom plates, the improvement comprising the expandable wall being made from an elastomer material and including a region preformed with a normally expanded shape outside bone.

55. A device according to claim 54 wherein the elastomer material includes polyurethane.

56. A device according to claim 54 wherein the wall includes a second region, spaced from the first-defined region, and preformed with a normally

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expanded shape outside bone.

5 57. A device according to claim 56
wherein the first-defined region and the second
regions, when further expanded beyond their respective
normally expanded shapes to reach a given inflation volume,
present a maximum diameter less than a sphere expanded to an
equal inflation volume.

5 58. A device according to claim 56
wherein the wall includes a third region,
preformed with a normally expanded shaped outside bone, and
positioned between the first-defined region and the second
region.

5 59. A device according to claim 58
wherein the first-defined region, the second
region, and the third region, when expanded beyond their
respective normally expanded shapes to reach a given
inflation volume, present a maximum diameter less than a
sphere expanded to an equal inflation volume.

60. A device according to claim 54
wherein the expandable region includes a further
expanded shape, outside bone, having a diameter greater than
the normally expanded shape.

61. A device according to claim 60
wherein the expandable region has a further
expanded shape inside bone that substantially corresponds to
the further expanded shape outside bone.

62. A device according to claim 54
wherein the elastomer material has an ultimate
elongation of greater than about 300%.

63. A device according to claim 54
wherein the elastomer material is resistant to
abrasion by cancellous bone.

64. A method for compacting cancellous bone
comprising the steps of
introducing into bone a device including an

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~~expanding the wall inside bone from the normally expanded shape to a further expanded shape to compact cancellous bone and form a cavity.~~

65. A method according to claim 64 and further including the step of filling the cavity with a material.

66. A method according to claim 65 and further including the step of removing the device from bone prior to the filling step.

67. A method according to claim 65
wherein the material comprises bone cement.

68. A method according to claim 65 wherein the material comprises synthetic bone substitute.

69. A method according to claim 65
wherein the material comprises a flowable material
that sets to a hardened condition.

70. A method according to claim 65
wherein the material comprises allograft tissue.

71. A method according to claim 65
wherein the material comprises autograft tissue.

72. A method according to claim 65 wherein the material comprises medication.

73. A method for treating a vertebral body having a top plate and a bottom plate comprising the steps of

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expanding the wall inside bone from the normally expanded shape to a further expanded shape to move at least one of the top and bottom plates.

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74. A method for manufacturing a device for compacting cancellous bone comprising the step of applying heat and pressure to a tube of an elastomer material to form a region having a normally expanded shape outside bone, which is expandable to a further expanded shape outside bone having a diameter greater than the normally expanded shape.

75. A method according to claim 74 wherein the elastomer material is resistant to abrasion by cancellous bone.

76. A method according to claim 74 wherein the elastomer material has a softening temperature greater than about 50° C.

77. A method according to claim 74 wherein the elastomer material has an ultimate elongation value of greater than about 300%.

78. A method according to claim 74 wherein the elastomer material possesses a tear strength value of greater than about 280 lbf/in for resistance to abrasion by cancellous bone.

79. A method according to claim 74 wherein the elastomer material possesses a Shore hardness value of less than about 100 A for elastomeric expansion within and resistance to abrasion by cancellous bone.

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